



PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re application of

Docket No: Q61622

Vojin JEREMIJEVIC

Appln. No.: 09/674,643

Group Art Unit: 3763

Confirmation No.: 8866

Examiner: Roz MAIORINO

Filed: November 02, 2000

For: DEVICE FOR PROTECTING AND NEUTRALIZING A NEEDLE FOR MEDICAL USE

SUBMISSION OF APPEAL BRIEF

MAIL STOP APPEAL BRIEF - PATENTS

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Sir:

Submitted herewith please find an Appeal Brief. Applicant is *reinstating* this appeal and has already paid the Appeal Brief Submission fee on December 27, 2005, no fee is due at this time. Accordingly, Applicant is not submitting the statutory fee of \$250.00.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

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WASHINGTON OFFICE

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CUSTOMER NUMBER

Date: March 30, 2005



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**APPEAL BRIEF UNDER 37 C.F.R. § 41.37**

**MAIL STOP APPEAL BRIEF - PATENTS**

Commissioner for Patents

P.O. Box 1450

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Sir:

In accordance with the provisions of 37 C.F.R. § 41.37, Appellant submits the following:

**Table of Contents**

I.	REAL PARTY IN INTEREST .....	2
II.	RELATED APPEALS AND INTERFERENCES.....	2
III.	STATUS OF CLAIMS .....	2
IV.	STATUS OF AMENDMENTS .....	2
V.	SUMMARY OF THE CLAIMED SUBJECT MATTER .....	3
VI.	GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL .....	5
VII.	ARGUMENT .....	5
VIII.	CONCLUSION.....	11
	CLAIMS APPENDIX.....	13
	EVIDENCE APPENDIX:.....	18
	RELATED PROCEEDINGS APPENDIX .....	19

APPEAL BRIEF UNDER 37 C.F.R. § 41.37  
U.S. Appln. No. 09/674,643

**I. REAL PARTY IN INTEREST**

The real party in interest is DEVICE RESEARCH AND DEVELOPMENT (DRD) (Assignee) by virtue of an assignment executed by the inventor (Appellant) on October 2, 2000, and recorded by the Assignments Branch of the U.S. Patent and Trademark Office on November 2, 2000 at Reel 012344, Frame 0088.

**II. RELATED APPEALS AND INTERFERENCES**

Upon information and belief, there are no other prior or pending appeals, interferences, or judicial proceedings known to Appellant, Appellant's representative or the assignee that may be related to, be directly affected by, or have a bearing on the Board of Patent Appeal's and Interference's (Board) decision on this appeal.

**III. STATUS OF CLAIMS**

Claims 1-3 and 15-36 are all the claims pending in the application. Claims 15-22 are allowed. Claims 1-3 and 23-36 presently stand rejected.

**IV. STATUS OF AMENDMENTS**

An Amendment under 37 C.F.R. 1.116 was filed on January 7, 2004, in Response to the Final Office Action dated November 28, 2003. As noted in the Advisory Action dated February 2, 2004, the Amendment filed January 7, 2004, will be entered.

A Supplemental Amendment under 37 C.F.R. 1.116 was filed on February 24, 2004. As indicated in the Advisory Action dated April 23, 2004, the Supplemental Amendment filed on February 24, 2004, will not be entered.

APPEAL BRIEF UNDER 37 C.F.R. § 41.37  
U.S. Appln. No. 09/674,643

An Appeal Brief was filed on December 27, 2004. A Final Office Action was mailed on February 22, 2005. This Appeal Brief is in response to this Final Office Action.

**V. SUMMARY OF THE CLAIMED SUBJECT MATTER**

A *non-limiting* embodiment of the invention is described below with references to the present specification. The device for protecting a needle is used to protect a health care worker from the sharp end 2 of a needle 1 when the needle 1 is not being used, and allows a sleeve 10 to be moved away from the sharp end 2 when the needle is being used.<sup>1</sup>

A first link 13 is able to take at least three positions when the needle is positioned vertically upright with the sharp end 2 of the needle 1 above a base end 3 of the needle 1: two equilibrium positions I, II and a locked position III.<sup>2</sup> The two equilibrium positions are an equilibrium starting position I and an equilibrium in-use position II. A first resilient hinge means 19 connects a first end 15 of the first link 13 to the sleeve. The resiliency of the first resilient hinge means allows the first link 13 to take up either an equilibrium in-use position II or an equilibrium starting position I when no force is applied to the link and the needle is positioned upright. In these equilibrium positions I, II, the link 13 makes an acute angle with respect to an axis of a through bore 11 of the sleeve 10.<sup>3</sup>

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<sup>1</sup> See Fig. 1.

<sup>2</sup> See Fig. 1.

<sup>3</sup> See Fig. 1 & page 3, line 25- page 4, line 30.

APPEAL BRIEF UNDER 37 C.F.R. § 41.37  
U.S. Appln. No. 09/674,643

A first crank arm 22, which has a length no greater than a length of the first link 13, is mounted so that its first end 24 pivots freely with a second end 17 of the first link 13 and its second end 26 pivots freely with a base means 21, which receives the base end 3 of the needle 1.

The device can also include a second link 14 connected to the sleeve 10, and a second resilient return hinge means 20 that connects a first end 16 of the second link to the sleeve 10 so that the second link 14 takes up a defined equilibrium position on a direction that makes an acute angle with the axis of the bore 11.<sup>4</sup> A second crank arm 23, which has a length no greater than a length of the second link 14, is mounted so that its first end 25 pivots freely with a second end 18 of the second link 14 and its second end 27 pivots freely with the base means 21.

***Means-plus-function Limitations***

Independent claim 1 and dependent claim 3 include the mean-plus-function limitations “first means for mounting each of said first and second ends of the first crank arm to pivot freely respectively on the second end of the first link and on the base means” and “second means for mounting each of said first and second ends of the second crank arm to pivot freely respectively on the second end of the second link and on the base means,” respectively.

The corresponding structures in the specification with respect to these limitations are the freely pivoting elements 28, 29, 30, 31 of the embodiment shown in Figs. 1-6 and the freely pivoting elements 128, 129, 130, 131 of the embodiment shown in Fig 7. These elements allow for *free pivoting* of the crank arms 22, 23, 122, 123. These free pivoting elements contrast with

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<sup>4</sup> See Figs. 2-5.

APPEAL BRIEF UNDER 37 C.F.R. § 41.37  
U.S. Appln. No. 09/674,643

the non-limiting embodiments of the resilient return hinge means 19, 20, 119, 120, which do not allow free pivoting, but instead are designed to take equilibrium positions.

**VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL**

Claims 1, 2, 23-31, and 33-36 are rejected under 35 U.S.C. 102(e) as allegedly being anticipated by Nestell (US 5,925,020).

Claims 3 and 32 are rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Nestell.

**VII. ARGUMENT**

As noted above, claims 1-3 and 23-36 stand rejected. It is respectfully submitted that claims 1-3 and 23-36 are patentable over Nestel for the following reasons.

***Claims 1-2, 23-25, 28-31, and 36 are Patentable Over Nestel***

Independent claim 1 recites a device for protecting a needle having *inter alia* a first link able to take at least three positions when the needle is positioned vertically upright with the sharp end of the needle above the base end of the needle, the three positions being an equilibrium starting position, an equilibrium in use position, and a locked position; a first resilient return hinge means for connecting the first end of the first link to the sleeve, a first crank arm; and a first means for mounting each of said first and second ends of the first crank arm to pivot freely respectively on the second end of the first link and on the base means. The resiliency of the first hinge means allowing said first link to takes up one of the equilibrium in use position and the equilibrium starting position, wherein the link makes an acute angle ( $\alpha$ ) with respect to the axis

APPEAL BRIEF UNDER 37 C.F.R. § 41.37  
U.S. Appln. No. 09/674,643

of the through bore, when no force is applied to the link, and the needle is positioned vertically upright with the sharp end of the needle above the base end of the needle.

**Nestell**

Nestell discloses a needle point barrier 10 having a link arm 38 and a hinge 46 that connects the link 38 to barrier arm 44. The barrier arm 44 is connected to a tip guard 50. The link arm 38 includes a longitudinally extending slot 42 through which the needle cannula 12 extends. A hinge 40 connects the link arm 38 to a spring arm 32. The proximal end 34 of the spring arm 32 is joined to a needle hub 18.<sup>5</sup>

Figs. 1 and 2 of Nestell show the needle point barrier 10 in a ready-to-use position. Fig. 3 shows a position of Nestell's link arm 38 past which the biasing forces exerted by the spring arm 32 propel the barrier arm 32 in the direction C to the position shown in Fig. 5. Prior to the position in Fig. 3, the biasing forces of the spring arm 32 exert a force in the direction opposite the direction C, i.e., towards the position in Figs. 1 and 2.<sup>6</sup>

Nestell's structure, in which the needle point barrier 10 includes both a barrier arm 44 and a link 38 provides Nestell's needle point barrier with a complicated structure. Furthermore, this structure creates a twisting force when the barrier arm 44 and link 38 pass from the position of Fig. 1 to the position of Fig. 5. Therefore, there is a risk that the needle 12 will twist or break if the needle is very thin, causing a danger to any health care worker who handles the needle.

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<sup>5</sup> See Nestell at Figs. 1-5.

<sup>6</sup> See Nestell at 4:27-61.

APPEAL BRIEF UNDER 37 C.F.R. § 41.37  
U.S. Appln. No. 09/674,643

Appellant sees no interpretation of Nestell's needle point barrier that meets all of the claim's recitations, as discussed below.

**Means for Mounting ... to Pivot Freely**

As an initial matter, the connection between the proximal end 34 of the spring arm 32 and the mounting collar 30 cannot be reasonably considered as corresponding to the means-plus-function limitation "first means for mounting each of said first and second ends of the first crank arm to pivot freely respectively on the second end of the first link and on the base means."<sup>7</sup> Specifically, Nestell's connection cannot be considered as a structure equivalent to the *freely pivoting* elements 30, 31 (which mount the links 22, 23 to the base 21, 209) of the embodiment shown in of the present specification Figs. 1-6 or the *freely pivoting* elements 130, 131 (which mount the links 122, 123 to the base 209) of the embodiment shown in Fig 7 of the present specification because Nestell's connection does not perform the *same function* as the recited "means for mounting ... to pivot freely."<sup>8</sup>

That is, Nestell's connection between the proximal end 34 of the spring arm 32 and the mounting collar 30 does not *pivot freely*, but is instead a *non-movable* connection.<sup>9</sup> The fact that Nestell's connection is non-movable allows the spring arm 32 to become deflected so that the spring arm 32 can provide a biasing force in order to return the spring arm to the flat position of

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<sup>7</sup> See MPEP 2181; *In re Donaldson Co.*, 16 F.3d 1189, 29 USPQ2d 1845 (Fed. Cir. 1994).

<sup>8</sup> See MPEP 2183; *Kemco Sales, Inc. v. Control Papers Co.*, 208 F.3d 1352, 54 USPQ2d 1308 (Fed. Cir. 2000).

<sup>9</sup> Compare Nestell's Figs. 2 & 5 with Fig. 3.

APPEAL BRIEF UNDER 37 C.F.R. § 41.37  
U.S. Appln. No. 09/674,643

either Nestell's Fig. 2 or Fig. 5.<sup>10</sup> Therefore, if Nestell's connection were to pivot freely instead of providing a biasing force, the needle point barrier 10 would not function properly.

**Resilient Return Hinge Means**

As an initial matter, the connection between Nestell's barrier arm 44 and tip guard 50 cannot be considered the recited "first resilient return hinge means" because the connection between the barrier arm 44 and tip guard 50 is not a *resilient* hinge, but is instead a non-movable connection.

It appears to be the Examiner's position that Nestell's link arm 38 corresponds to the recited "first link," that the hinge 46 corresponds to the recited "first resilient return hinge means," that the spring arm 32 corresponds to the recited "first crank arm." However, Nestell's link arm 38 cannot reasonably correspond to the claimed "first link" because the link 38 is not able to take at least three positions (an equilibrium starting position, an equilibrium in use position, and a locked position) when no force is applied to the link 38. Instead, the link 38 assumes either the position shown in Fig. 1 or the position shown in Fig. 5.<sup>11</sup> The embodiment of Figs. 1-5 of Nestell has a non-locking tip in which it is impossible to know if the needle has or has not been utilized. Therefore the needle is always dangerous to the ill patient. Although Figs. 6 and 7 appear to show an alternative embodiment in which the equilibrium position shown in Fig. 5 is a locked position, this is not an additional position, but is the same position as one of the two equilibrium positions.

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<sup>10</sup> See Nestell at 3:26-40.

<sup>11</sup> See Nestell at 4:37-61.

APPEAL BRIEF UNDER 37 C.F.R. § 41.37  
U.S. Appln. No. 09/674,643

Accordingly, it is respectfully submitted that independent claim 1 is patentable, and that dependent claims 23-25, 28-31, and 36 are patentable at least because of their dependency from claim 1.

***Claims 3, 26, and 32-35 are Patentable Over Nestel***

It is also respectfully submitted that claim 3 is patentable over Nestel at least because of its dependency from claim 1 and for the following reasons.

Dependent claim 3 recites a device for protecting a needle having *inter alia* a first and second links; first and second resilient return hinge means, first and second crank arms, and first and second mounting means. The device of claim 3, which has two links, two hinge means, two crank arms, and two mounting means, allows a health care worker to apply one finger on each of the crank arms when adjusting the device.

The Examiner acknowledges that Nestell does not teach first and second links. However, the Examiner states that “it would have been obvious to Duplicate the link member and the cracker arm for multiple effect,” relying on *In re Harza*.<sup>12</sup> As an initial matter, there is no objective evidence of record regarding any motivation or suggestion to modify Nestell’s needle point barrier 10 so that it would include multiple links, hinge means, crank arms, and mounting means.<sup>13</sup>

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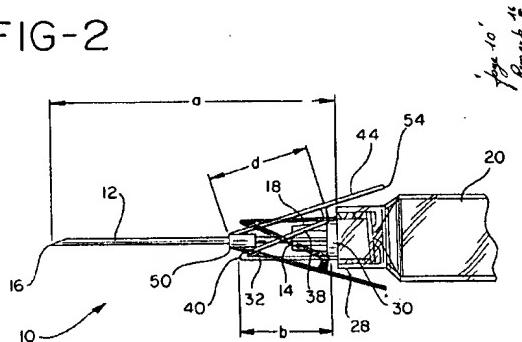
<sup>12</sup> *In re Harza*, 274 F.2d 669, 124 USPQ 378 (CCPA 1960).

<sup>13</sup> See, *In re Sang Su Lee*, 277 F.3d 1338, 1343, 61 USPQ2d 1430, 1443 (Fed. Cir. 2002), citing, e.g., *In re Dembiczak*, 175 F.2d 1340, 1342, 50 USPQ2d 1614, 1617 (Fed. Cir. 1999) (“Our case law makes clear that the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references.”). In *Lee*, the Federal Circuit further emphasized that the “need for specificity pervades this authority.” (*Lee*, 277 F.3d at 1343, 61 USPQ2d at 1433 (citing *In re Kotzab*, ... (footnote continued)

APPEAL BRIEF UNDER 37 C.F.R. § 41.37  
U.S. Appln. No. 09/674,643

Moreover, the Examiner relies on *In re Harza* for its holding that a “mere duplication of parts has no patentable significance unless a new and unexpected result is produced.”<sup>14</sup> However, the modification of Nestell’s proposed needle point barrier 10 proposed by the Examiner is not a mere, or simple, duplication. As discussed above, Nestell’s function is predicated on the deflection of the link arm 38, which has a slot 42 through which the needle cannula 12 extends.<sup>15</sup> Accordingly, if Nestell’s structure were modified in the manner proposed by the Examiner (i.e., to have two link arms 38 with slots 42), the principle of operation of the needle point barrier 10 would be change because the multiple link arms with slots would interfere with one another.<sup>16</sup> In fact, as shown in the *modified* Fig. 2 of Nestell, below, a mere duplication of Nestell’s barrier arm 44, link arm 38, and spring arm 32 would be almost impossible.

FIG-2



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217 F.2d 1365, 55 USPQ2d 1313, 1317 (Fed. Cir. 2000) (“particular findings must be made as to the reason the skilled artisan, with no knowledge of the claimed invention, would have selected these components for combination in the manner claimed”)).

<sup>14</sup> *In re Harza*, 274 F.2d at 671, 124 USPQ at 380.

<sup>15</sup> See Nestell at 3:26-55 & Figs. 1-5.

<sup>16</sup> See *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959); MPEP § 2143.01.

APPEAL BRIEF UNDER 37 C.F.R. § 41.37  
U.S. Appln. No. 09/674,643

Accordingly, it is respectfully submitted that dependent claims 3 is patentable. In addition, it is respectfully submitted that dependent claims 26 and 32-35 are patentable at least because of their dependency from claims 1 and 3.

***Claim 27 is Patentable Over Nestel***

Finally, it is respectfully submitted that claim 27 is patentable over Nestel at least because of its dependency from claims 1 and 3, and because Nestell does not teach or suggest that the first and second links and the first and second crank arms are situated substantially in a common plane and form substantially a quadrilateral whose diagonals are substantially perpendicular.

As an initial matter, as discussed at MPEP §2144.04, it is inappropriate for the Examiner to rely solely on case law when Applicant has demonstrated a criticality to the specific limitation. In fact, the specification states that this recited device for protecting a needle is a “structure is symmetrical and thus balanced, thereby improving its operation.” Accordingly, the Examiner’s unsupported rejection of claim 27 is *prima facie* improper.

In addition, even *assuming arguendo* that Nestell’s needle point barrier 10 could be modified to have two links and two crank arms, there is clearly no motivation or suggestion that this modified structure would be “a situated substantially in a common plane and form substantially a quadrilateral whose diagonals are substantially perpendicular.”

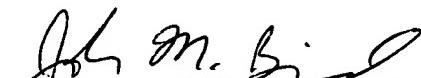
**VIII. CONCLUSION**

It is respectfully requested that the Board of Appeals and Interferences reverse the Examiner’s rejection with respect to claims .

APPEAL BRIEF UNDER 37 C.F.R. § 41.37  
U.S. Appln. No. 09/674,643

Because the Appellant has already submitted the fee for the Appeal Brief on December 27, 2004, Appellant believes that no fee is necessary in order to reinstate the Appeal. However, the USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,



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**CLAIMS APPENDIX**

**CLAIMS 1-3 AND 23-36 ON APPEAL:**

1. A device for protecting a needle for medical use or the like, the needle having a sharp end and a base end, comprising:

a sleeve having a through bore defined on a given axis, said through bore being of a section that is not less than that of the needle to be protected;

a first link having first and second ends, said link being of a length " $L_1$ " defined between said two ends, wherein the first link is able to take at least three positions when the needle is positioned vertically upright with the sharp end of the needle above the base end of the needle, the three positions being an equilibrium starting position, an equilibrium in use position, and a locked position;

a first resilient return hinge means for connecting the first end of the first link to the sleeve, the resiliency of said first hinge means allowing said first link to take up one of the equilibrium in use position and the equilibrium starting position, wherein the link makes an acute angle ( $\alpha$ ) with respect to the axis of the through bore, when no force is applied to the link, and the needle is positioned vertically upright with the sharp end of the needle above the base end of the needle;

a base means suitable for receiving the base end of the needle to be protected;

a first crank arm, said first crank arm being defined between first and second ends, said crank arm being of a length " $I_1$ " defined between its two ends, the length " $I_1$ " of the first crank arm being no greater than the length " $L_1$ " of the first link; and

APPEAL BRIEF UNDER 37 C.F.R. § 41.37  
U.S. Appln. No. 09/674,643

first means for mounting each of said first and second ends of the first crank arm to pivot freely respectively on the second end of the first link and on the base means.

2. A device according to claim 1, further including strut means connecting said link to said crank arm when they are in a first position, said strut means including a weak point making it possible, on application of a given force, to break said strut means at said weak point.

3. A device according to claim 1, further including:  
a second link having first and second ends, said second link being of a length “ $L_2$ ” defined between said two ends;  
second resilient return hinge means for connecting the first end of the second link to the sleeve, said second hinge means being organized so that said second link takes up a defined equilibrium position on a direction that makes an acute angle ( $\alpha'$ ) with the axis of the through bore;  
a second crank arm, said second crank arm being defined between first and second ends, said second crank arm being of a length “ $I_2$ ” defined between its two ends, the length “ $I_2$ ” of the second crank arm being no greater than the length “ $L_2$ ” of the second link; and  
second means for mounting each of said first and second ends of the second crank arm to pivot freely respectively on the second end of the second link and on the base means.

APPEAL BRIEF UNDER 37 C.F.R. § 41.37  
U.S. Appln. No. 09/674,643

23. A device according to claim 1, wherein the base means comprises two first and second rings, the first ring receiving the base end of the needle, and means for connecting said two rings between them by weak points.

24. A device according to claim 23, wherein the two rings respectively include two openings, the two openings being realized to form, when the two rings are connected between them, a female part of a male-female jointing able to cooperate with the complementary male part constituted by an end-part of a syringe, the total depth of these two openings, when the two rings are connected between them, being lower than the height of the end-part of the syringe.

25. A device according to claim 23, further including a not-withdrawal ring located on a wall of said second ring.

26. A device according to claim 3, wherein the lengths " $L_1$ " and " $L_2$ " are substantially equal to common value "L" and that the lengths " $I_1$ " and " $I_2$ " are substantially equal to a common value "I".

27. A device according to claim 3, wherein the first and second links and the first and second crank arms are situated substantially in a common plane and form substantially a quadrilateral whose diagonals are substantially perpendicular, the diagonal interconnecting the vertices of the quadrilateral situated respectively at the sleeve and at the base means coinciding substantially with the axis of the through bore.

APPEAL BRIEF UNDER 37 C.F.R. § 41.37  
U.S. Appln. No. 09/674,643

28. A device according to claim 1, wherein at least two of the following elements are made of the same material: sleeve; base means; link; crank arm; hinge means; and freely pivoting mounting means.

29. A device according to claim 28, wherein said at least two elements are made by molding.

30. A device according to claim 29, wherein the material is a plastics material.

31. A device according to claim 1, wherein the length “ $L_1$ ” of the link and the length “ $I_1$ ” of the crank arm are determined in such a manner than the sum  $L_1+I_1$  and the sum  $L_1+I_1+M_1$ , where “ $M$ ” represents the length of the sleeve, bracket the length “ $A$ ” of the needle to be protected as measured between the sharp end and the base end.

32. A device according to claim 3, further including a casing made of a resilient material surrounding under tension the assembly constituted by the sleeve, the first and second links, the first and second hinge means, the first and second crank arms, the first and second means for mounting the first and second ends of the first and second crank arms to pivot respectively on the second ends of the first and second links and on the base means, and at least a portion of the base means.

APPEAL BRIEF UNDER 37 C.F.R. § 41.37  
U.S. Appln. No. 09/674,643

33. A device according to claim 32, wherein the resilient material from which the casing is made is transparent.

34. A device according to claim 32, further including a sachet made of a non-stretch material, the sachet containing a given substance and being capable of tearing under a given traction, and means for securing the sachet and the casing substantially at two opposite points of the inside wall of the casing, the two said points being situated substantially facing the first means for mounting the first ends of the first and second crank arms to pivot freely on the second ends of the first and second links.

35. A device according to claim 34, wherein the substance contained in the sachet presents at least one of the following properties: being suitable for absorbing at least a portion of visible light, being suitable for hardening, being suitable for sterilizing.

36. A device according to claim 1, further including, for neutralizing said needle, snap-fastening means to lock said link and said crank arm relative to each other in a second given position.

APPEAL BRIEF UNDER 37 C.F.R. § 41.37  
U.S. Appln. No. 09/674,643

**EVIDENCE APPENDIX:**

Pursuant to 37 C.F.R. § 41.37(c)(1)(ix), submitted herewith are copies of any evidence submitted pursuant to 37 C.F.R. §§ 1.130, 1.131, or 1.132 or any other evidence entered by the Examiner and relied upon by Appellant in the appeal.

NONE

APPEAL BRIEF UNDER 37 C.F.R. § 41.37  
U.S. Appln. No. 09/674,643

**RELATED PROCEEDINGS APPENDIX**

Submitted herewith are copies of decisions rendered by a court or the Board in any proceeding identified about in Section II pursuant to 37 C.F.R. § 41.37(c)(1)(ii).

NONE